DECLARATION OF KOON-WAH LEONG UNDER 37 C.F.R. §1.131	Application Number	09/593,827
	Confirmation Number	7505
	Filing Date	June 13, 2000
Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	First Named Inventor	Sherry X. Guo
	Examiner	R. Gitomer
	Group Art	1623
	Attorney Docket No.	LIFE008/LFS-101

This Declaration and the attached Exhibit are being submitted in conjunction with the Applicants' Response to the Office Action dated June 16, 2003.

I, Koon-wah Leong, Ph.D., do hereby declare as follows.

1.   I am an inventor of the invention claimed in the above captioned application, along with Sherry Guo.

2.   I have been asked to declare and provide factual evidence in support of a reduction to practice of a storage stable composition containing nylon and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine before October 26, 1999.

3.   As evidenced by Exhibit A, we reduced to practice a storage stable composition containing nylon and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine prior to October 26, 1999. The dates have been redacted from Exhibit A. All redacted dates are prior to October 26, 1999.

1

4.   Exhibit A consists of a photocopy of three pages from my lab notebook, showing an experiment that I performed called "Trial 3". The following is written at the end of page 651-105: "Rgt II was coated on OneTouch Nylon membrane at 65°C for 10 min". As is apparent from the middle of page 651-105, Rgt II contains B dip. B dip contains component DA-67, which corresponds to 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine. As such, this page discloses a nylon membrane coated with 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine. Pages 651-106 and 651-107 show test results, and concludes with "Conclusion: very good calibration curve was obtained". According to my lab notebook, the membrane was coated with DA-67 prior to October 26, 1999. The date of the signature at the bottom of the page is also prior to October 26, 1999.

5.   The evidence provided in Exhibit A establishes that we produced a storage stable composition containing nylon and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine prior to October 26, 1999.

6.   I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

        Respectfully submitted,

Date: September 9, 2003   Koon-wah Leong
                                           Koon-wah Leong, Ph.D.
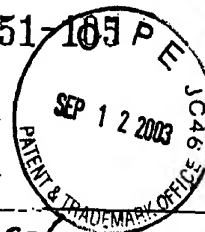

        Attachments: Exhibit A

2

LIFESCAN INCORPORATED   EXHIBIT A 1/3   № 651-185 PE
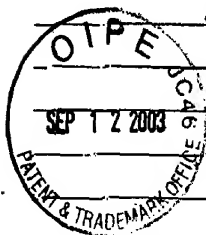
DATE_____ PROJECT_____ 09/593,827

SUBJECT_____ From Page No. 104

When the above strips were tested, no blue color
was observed due to the inhibition of KAO by Bis-MAPS-C3.

Trial 3 :

Rgt I : { 200 mg/ml of protease XII
          4% mannitol
          0.5% Triton X-100
          5mM Ca(Ac)$_2$
          in 0.1M EPPS, pH = 8.0.

Rgt I was coated on Rubicon strip version 3.   2-layer
Coating was applied. (coated on

Rgt II : A dip { 2.06 u/ml KAO
                 1 mg/ml HRP.
                 4% mannitol
                 1% PVP 360K.
                 in 0.1M phosphate, pH = 7.5.

          B dip { 1mM DA-67 in 70% methanol, 30% H$_2$O

Rgt II was coated on One-touch Nylon membrane
@ 65°C for 10 min.

** Yellow soln. was observed when B dip was coated

One-touch Nylon membrane was mounted on One strip
strip holder.

Data On Disk No._____ Cont'd. on page_____

Signed_____ Date_____

Read and Understood_Sunyma Qian___ Date_____

Nº 651-106
4089423825   T-682 P.004/005 F-165
~~EXHIBIT A~~
EXHIBIT A 2/3 09/593,827
LIFESCAN INCORPORATED

DATE_____ PROJECT_____
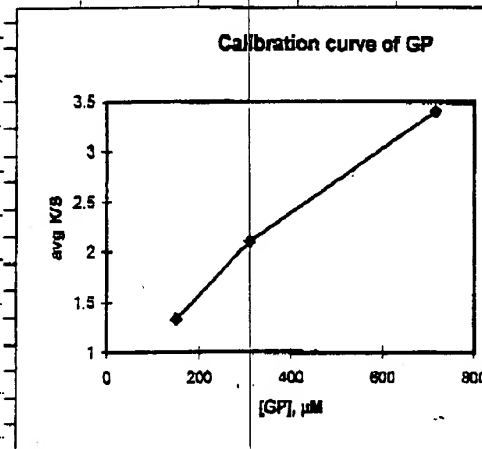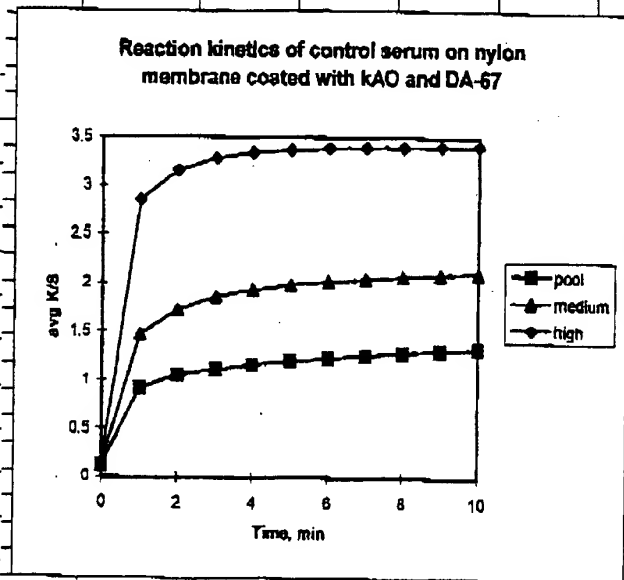
SUBJECT_____ From Page No. 104

Testing Procedures:

① 1 µl of control serum was added to Rubicon strips coated w/ Rgt I. The strips were then put on 37°C heating plate for 20 min

② 25 µl digested serum pooled for 5 Rubicon strips were then added to ~~one~~ strips coated w/ Rgt I.

③ The color product was monitored on Madge 18

Result 3

Reaction kinetics of control serum on nylon membrane coated with kAO and DA-67

avg K/S vs Time, min
— pool
— medium
— high

Calibration curve of GP

avg K/S vs [GP], µM

Data On Disk No._____ Cont'd. on page_____

Signed_____ Date_____

Read and Understood _Eugene Qian_ Date_____

LIFESCAN INCORPORATED   EXHIBIT A 3/3   N⁰ | 651-107

DATE_____ PROJECT_____ _____ 09/593,827

SUBJECT_____ From Page No. 104
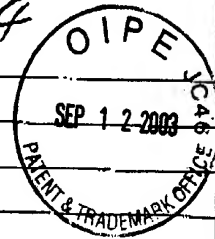
		A=660nm				
	[Time] min	R%1	R%2	K/S1	K/S2	avg K/S
Standard			87.95			
Pool serum 070797	Time, min					pool
150uM by GlvPro	0	62	62	0.116452	0.116452	0.116452
	1		28.12		0.918694	0.918694
	2	26.54	25.47	1.016649	1.090444	1.053546
	3	25.55	24.81	1.084697	1.139366	1.112032
	4	24.85	24.18	1.136322	1.188725	1.162524
	5	24.33	23.71	1.176726	1.227365	1.202045
	6	23.94	23.33	1.208255	1.259813	1.234034
	7	23.59	23.03	1.237492	1.286231	1.261862
	8	23.3	22.74	1.262423	1.312469	1.287446
	9	23.05	22.5	1.284447	1.334722	1.309585
	10	22.81	22.25	1.306071	1.358441	1.332256
Medium 1 090397	Time, min					medium
310 uM by GlvPro	0	62	62	0.116452	0.116452	0.116452
	1	20.2	22.22	1.576248	1.361325	1.468786
	2	18.38	19.63	1.812248	1.645272	1.72876
	3	17.67	18.45	1.918005	1.802277	1.860141
	4	17.31	17.82	1.975054	1.894936	1.934995
	5	17.05	17.45	2.017801	1.95258	1.98519
	6	16.87	17.19	2.048191	1.994618	2.021404
	7	16.72	17.02	2.074031	2.02282	2.048425
	8	16.59	16.88	2.096814	2.046485	2.07165
	9	16.48	16.78	2.116381	2.063638	2.090009
	10	16.38	16.69	2.134403	2.079256	2.106829
High 090397	Time, min					high
716 uM by GlvPro	0	62	62	0.116452	0.116452	0.116452
	1	12.47	14.03	3.071973	2.633942	2.852957
	2	11.78	12.64	3.303382	3.018896	3.161139
	3	11.53	12.16	3.394163	3.172642	3.283403
	4	11.37	12	3.454387	3.226667	3.340527
	5	11.33	11.88	3.469713	3.268154	3.368933
	6	11.28	11.83	3.489024	3.285893	3.387358
	7	11.26	11.81	3.496797	3.29275	3.394774
	8	11.25	11.79	3.500694	3.299832	3.400263
	9	11.23	11.77	3.50851	3.306938	3.407724
	10	11.22	11.76	3.512428	3.310501	3.411464

Conclusion:

Very good calibration curve was obtained. However, the interference still need to be checked.

Data On Disk No._____ Cont'd. on page_____

Signed_____ Date_____

Read and Understood _Snyue Qians_ Date_____